

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,628	12/20/1999	THOMAS J. BURKE	PANVERA.003.	2628
7	590 02/08/2002			
ATTORNEY FOR APPLICANT c/o VERTEX PHARMACETICALS INCORPORATED 130 WAVERLY STREET CAMBRIDGE, MA 02139			EXAMINER	
			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
		1646	91	
			DATE MAILED: 02/08/2002	•

Please find below and/or attached an Office communication concerning this application or proceeding.

· · ·		Application No.		Applicant(s)			
Office Action Summary		09/467,628		BURKE ET AL.			
		Examiner		Art Unit			
		Joseph F Murphy	,	1646			
	The MAILING DATE of this communication app						
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)	Responsive to communication(s) filed on <u>06 D</u>	December 2001 .					
2a)□		is action is non-fi	nal.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠	Claim(s) 1-12 is/are pending in the application						
4a) Of the above claim(s) <u>9-12</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠	Claim(s) <u>1-8</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10)	Γhe drawing(s) filed on is/are: a)□ accep	oted or b)□ objecte	ed to by the Exa	miner.			
	Applicant may not request that any objection to the	e drawing(s) be hel	d in abeyance. S	ee 37 CFR 1.85(a).			
11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	4)		v (PTO-413) Paper No(s) Patent Application (PTO-152)			

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8 in Paper No. 6, 12/6/2001 is acknowledged. The traversal is on the ground(s) that i) the inventions are not distinct and ii) there is no burden to search. This is not found persuasive because, in response to argument i) Applicant's attention is directed to MPEP 808.02 which states that "Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05 (c-i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof; (B) A separate status in the art when they are classifiable together; (C) A different field of search." As set forth in the Restriction requirement, Group I is classified in class 435, subclass 7.8; Group II is classified in class 536, subclass 25.32. The separate classification established for each Group demonstrates that each distinct Group has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Thus, the Restriction requirement is proper.

Response to argument ii): Applicant argues that no burden is placed on the examiner to consider all claims. As discussed above, the separate classification established for each Group demonstrates that each distinct Group requires a separate field of search, and a search of one Group would not reveal art on the other Group, thus imposing a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL. Claims 9-12 are withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-87 are under consideration.

Application/Control Number: 09/467,628

Art Unit: 1646

Claim Rejections - 35 USC § 112(2)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation in subsection (e) of the term "any interaction" because it is unclear what interaction is being measured. Claims 2-8 are rejected insofar as they depend on the recitation in claim 1 of "any interaction".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (1992) in view of U.S. Patent No. 5,445,935 (Royer).

Hwang et al. teaches the synthesis of a number of tetrahydrochrysene fluorescent ligands for the estrogen receptor (see Chart 1, page 11538). Hwang et al. teaches methods of measuring binding of these fluorescent ligands to the ER, in the presence of a molecule that may compete with their binding, in this case estradiol (see Figure 6, page 11542). Hwang et al. does not teach the use of fluorescently labeled DNA in the assay.

Application/Control Number: 09/467,628

Art Unit: 1646

Page 4

The '935 patent discloses a method of assaying the binding of ER to fluorescently labeled estrogen response element DNA, measured by fluorescent polarization (column 11, line 1 to column 12, line 14). It would have been obvious to one of skill in the art at the time the invention was made to practice a method of measuring by fluorescent polarization the binding activities of molecules to steroid hormone receptors, specifically the ER, using fluorescent ligands and fluorescently labeled DNA. The motivation is provided in the '935 patent which

teaches that the disclosed assay methods may be used to test quantitatively the effects of specific

ligands or other drugs on formation of complexes between proteins an nucleic acids.

Conclusion

No claim is allowed.

DAVID S. ROMEO

Art Unit: 1646

Advisory Information

Page 5

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.

Patent Examiner

Art Unit 1646

February 7, 2002